

c.) Remarks

Claims 1, 28, 30 and 32 have been amended in order to recite the present invention with the specificity required by statute. Additionally, claims 2-22, 25-27, 29 and 31 are amended for better dependency and/or idiomatic usage, and new claims 33 and 34 are presented in order to more specifically recite various preferred embodiments of the present invention. The subject matter of the amendment may be found in the specification as filed, *inter alia*, at page 17, lines 15-28. Claims 33 and 35 are original claims 23 and 24, respectively. Accordingly, no new matter has been added.

In the July 3, 2003 Office Action the Examiner states claims 1-4, 7, 14-19, 21-22 and 25-31 are under consideration; claims 5-6, 8-13, 20 and 32 being withdrawn from consideration as drawn to nonelected species. The Examiner states "Applicant [sic] timely traversed the restriction (election) requirement in paper No. 8."

Of course, there was no Restriction Requirement; on July 26, 2001 the Examiner required that Applicants select for search a single species among claims 22-24. In any event, in paper No. 8 Applicants noted that the selection of species requirement was improper since dependent claim 23 only adds density unit limitations to the materials in antecedent claim 22 (and claim 24 simply recites one preferred embodiment). In the September 7, 2001 Office Action the Examiner agreed ("This [Applicants' traversal] has

been found persuasive”<sup>1</sup>); however, Applicants already inadvertently cancelled claims 23 and 24.<sup>2/</sup>

However, while Applicants’ traversal was found persuasive, claims 5-6, 8-13, 20 and 32 are for some reason still currently withdrawn from prosecution. The undersigned does not understand why from the record, and so, clarification is respectfully requested.

Of course, even if the selection of species requirement is maintained, the search of other species within the generic linking claim is mandated if the selected species is found to be allowable (MPEP § 809.04) and upon the ultimate allowance of any generic claim; rejoinder and consideration of any properly dependent claim are respectfully requested. MPEP § 809.02(e).

The Examiner will appreciate the undersigned is new to this application. Accordingly, to benefit both the undersigned and the record, Applicants believe it will be helpful to briefly review as well the fairly extensive prosecution history of this relatively straightforward invention.

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<sup>1/</sup> The Examiner also wrote that the selection of species requirement should have included claim 21 as well. In this regard, it is frankly not well-understood what species the Examiner was referring to. (“Claims are definitions of inventions. *Claims are never species.*” MPEP § 806.04(e). (Emphasis in original.)) Nonetheless, it is thought from subsequent prosecution (see the Office Action dated November 22, 2002 at page 2, lines 8-10) the Examiner was soliciting Applicants’ selection of a particular: water-soluble polymer, taste-masking agent and active agent.

<sup>2/</sup> For this reason, claims 23 and 24 are re-presented as new claims 33 and 34.

The Examiner originally rejected claims 1-22 and 25-27 (all claims pending) under 35 USC 103 as being obvious over a combination of U.S. Patents Nos. 4,788,055 (to Fischer) and 5,411,945 (to Ozaki). Fischer was said to teach a sustained release composition of dextromethorphan (active agent) and sulphonated polymer ion-exchange resin whereas Ozaki was said to teach a consumable film containing pullulan (water-soluble polymer).

During a Personal Interview conducted August 9, 2002 the Examiner kindly indicated that agreement was reached, e.g., “[t]he [proposed] amendment to claim 1 to the specific ratio overcomes the rejection over prior art.” The Examiner suggested the claims recite a particular taste masking agent as well. While it was not clear why this was necessary, Applicants filed an Amendment on September 10, 2002 presenting the specific ratio range discussed and reciting various taste masking agents, e.g., ion exchange resin, magnesium trisilicate, acrylic resin, cellulose ether, cellulosic and ethyl cellulose.

On September 26, 2002 the Examiner refused to enter the Amendment because the terms acrylic resin, cellulose ether, cellulosic and ethyl cellulose supposedly constituted new matter.

On October 9, 2002 Applicants filed a further Amendment which presented claims that specified the taste masking agent is an ion exchange resin. On October 11, 2002 the Examiner refused to enter that amendment because “the newly-submitted ratio of about 2:1 to about 1:2 requires further consideration and search.” This too was not well-understood, since this ratio was the very limitation discussed on August 9, 2002 that led to agreement on the claims. Nonetheless, an RCE was filed together with a still further

Amendment re-presenting acrylic resin, cellulose ether, cellulosic and ethyl cellulose and pointing out their foundation in the original specification.

The Examiner then issued on November 22, 2002 an Office Action withdrawing claims 1-13, 20 and 25-27 from prosecution and rejecting claims 14-19, 21-24 and 27-31 under 35 USC 112 for indefiniteness and under 35 USC 103 as obvious over the combination of U.S. Patents Nos. 5,980,882 (to Eichman) in view of Ozaki. On May 22, 2003 Applicants traversed the art rejection and on July 3, 2003, the Examiner rejected claims 25-27 only for indefiniteness and made the obviousness rejection over Eichman and Ozaki final.

These rejection are addressed, herein, in turn.

As to the rejection of claims 25-27, such has been attended to in the foregoing amendment. In particular, the terms "water soluble ingredients" (claim 25) and "at least one" (claims 25-27) have been deleted. Additionally, claim 27 is amended to recite the pharmaceutically active agent and taste masking agent as requested by the Examiner.

This leaves only the rejection for obviousness.

In support of the rejection under 35 USC 103, the Examiner states Eichman teaches a 2:1 dextromethorphan drug-resin complex that may be coated with Ozaki's pullulan film forming material. Supposedly,

"a person having ordinary skill in the art at the time the instant invention was made would have been motivated to use pullulan as a film-forming material in a drug-resin complex [as] disclosed by Eichman because the results

obtained by such a combination would have been expected.”

Respectfully submitted, this is insufficient. That is, there is absolutely no basis in fact on this record that the skilled artisan would have “expected” some particular results, let alone the results propounded by the Examiner. Moreover, there is no basis in fact that the skilled artisan would have desired such results at the time the present invention was made. Accordingly, there is simply no *prima facie* case of obviousness

Nonetheless, even if, *arguendo*, there was found, on the record, motivation to combine the teachings of Eichman and Ozaki, such combination still fails in any event to provide all the features of the pending claims. Accordingly, there is no *prima facie* obviousness on this basis either.

As the Examiner will appreciate, the present invention relates to a solid film adapted to adhere and dissolve in the mouth, e.g., which is orally consumable. In contrast, the proposed combination of prior art provides at best a viscous drug resin complex. This was pointed out previously and, in response the Examiner states in the Office Action:

“[t]his argument has not been found persuasive. Note that the specification fails to provide definition of the terminology ‘a consumable film adapted to adhere and dissolve in the mouth.’ Therefore, said terminology encompasses a complex coated with a film outer layer disclosed by the cited references.” (Emphasis added.)

First, the "cited references" do not disclose a film outer layer-coated complex; the Examiner's combination does. Second, and more importantly, the terms the Examiner refuses to accord patentable weight are well-known to those of ordinary skill.<sup>3/</sup>

That is, to the extent the Examiner still contends the terminology is repugnant to the skilled artisan, Applicants wish to point out there are a myriad of known "consumable films adapted to adhere and dissolve in the mouth". Just as one example, see, e.g., U.S. Patent No. 6,596,298. See also WO 99/17753, WO 98/26780, WO 98/20862 and WO 98/26763, each of which utilizes this terminology as well.<sup>4/</sup> Accordingly, it is clear those of ordinary skill are very well-versed, i.e., familiar, with this terminology.

Additionally, Applicants further wish to point out that

- the written description includes what the specification is understood to include by those of ordinary skill (Ralston Purina Co. v. Far-Mar-Co., Inc., 227 USPQ 177 (Fed. Cir. 1985)) and
- finding the exact words used is unimportant (In re Wright, 9 USPQ2d 1649 (Fed. Cir. 1989)).

As noted, the Examiner has made no attempt to show those of ordinary skill would not understand the terminology, as is required by the PTO Board of Patent Appeals and Interferences (fn. 3, *supra*).

In any event, it is, Applicants presume, undisputed that the Examiner

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<sup>3/</sup> In any event, the Examiner also has the burden of explaining why those skilled in the art would not recognize in the specification disclosure a description of the invention defined in the claims (Ex parte Sorenson, 3 USPQ2d 1462 (BPAA 1987)). The Examiner has not attempted to meet this burden.

<sup>4/</sup> And each of which was cited in Applicants' March 23, 2000 Information Disclosure Statement and is of record herein.

acknowledges the skilled artisan understands the term “film” at least. Accordingly, that feature must be provided patentable weight. As such, the record illustrates the prior art still does not provide the features of the claimed invention.

The Examiner cites Eichman for teaching dextromethorphan-resin mixtures at ratios of 2:1 to 1:2 at column 17, lines 4-11. However, these are not films as required by the pending claims --Eichman teaches suspensions. See column 17, lines 4 and 25.

Nor is this feature shown in Ozaki since even if pullulan (column 1, lines 18-25) is incorporated in Eichman as the Examiner urges, such would not necessarily provide a “film” as argued in the Office Action. Instead, such would form any of a viscous solution, a solid pellet, or thickened mass.

Although pullulan could in theory be utilized to form a film, there is simply no reason of record (1) why it would be advantageous to so modify Eichman, nor is there any reason of record why the skilled artisan would (2) utilize pullulan in the proportions necessary to create a solid rather than a gel or thickened suspension, let alone (3) produce a film from such material rather than a tablet or the like. Accordingly, if the Examiner is relying on his personal knowledge, then he is respectfully requested to

“provide an affidavit or declaration setting forth specific factual statements and explanation to support the finding. See 37 C.F.R. §1.104(d)(2).” MPEP §2144.03.

Without such affidavit or declaration, respectfully submitted, the claims must be allowed and this case passed to issue.

In view of the above amendments and remarks, Applicants submit that all of the Examiner’s concerns are now overcome and the claims are now in allowable condition.

Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 1-22 and 25-34 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,



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